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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,337	01/28/2005	Kevin R. Lynch	00812-03	5792
23322	7590	10/05/2006		EXAMINER
				FREISTEIN, ANDREW B
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/523,337	LYNCH ET AL.
	Examiner Andrew B. Freistein	Art Unit 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 September 2006.
- 2a) This action is **FINAL**.                                   2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-20,22,26-28,31 and 34-43 is/are pending in the application.
- 4a) Of the above claim(s) 26-28,31,35-37 and 40-43 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11-20,22,34,38 and 39 is/are rejected.
- 7) Claim(s) 11-20, 22, 34, 38 and 39 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/25/05.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

The amendment filed 09/14/2006 was entered. Claims 11-20, 22, 26-28, 31 and 34-43 are pending. Claims 1-10, 21, 23-25, 29, 30 and 32-33 were cancelled.

### *Priority*

This application is a 371 of PCT/US03/23768, filed 07/30/2003, which claims benefit of US provisional application no. 60/399,545, filed 07/30/2002 and US provisional application no. 60/425,595, filed 11/12/2002.

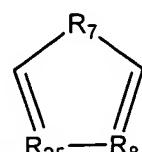
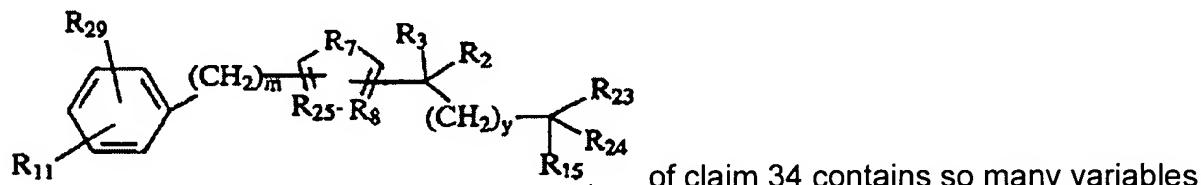
### *Information Disclosure Statement*

Applicant's information disclosure statement (IDS), filed on 04/25/2005, has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

### *Restriction Requirement*

In a response filed 09/14/2006, Applicant elected (with traverse) Group V, claims 11-20, 22, 34, 38 and 39. Applicant traverses the restriction requirement asserting that the amended claims are linked to form a general inventive concept.

Examiner respectfully disagrees with Applicant. The formula



that there is no defined technical feature. Specifically, in the structure  $R_{25}-R_8$ ,  $R_{25}$ ,  $R_7$  and  $R_8$  are independently selected from O, S,  $CHR_{26}$ ,  $CR_{26}$ ,  $NR_{26}$  and N, which

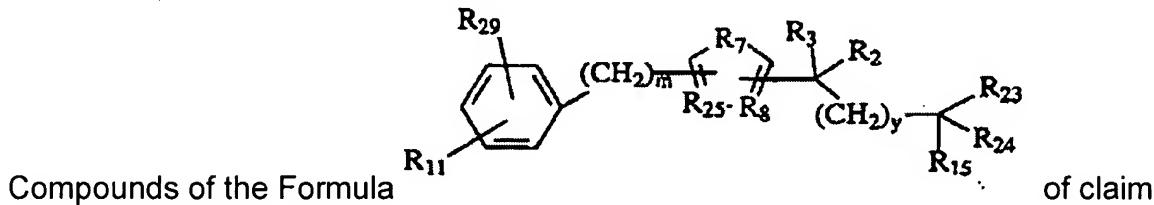
depict patentably distinct compounds. Thus, there is no core structure and thus no special technical feature.

#### ***Status of the Claims***

Claims 11-20, 22, 34, 38 and 39 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

#### **Elected and Examined Subject Matter**

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



34, wherein:

**R<sub>11</sub>, R<sub>20</sub>, R<sub>29</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>23</sub> and R<sub>24</sub>** are each as defined in claim 34;

**R<sub>25</sub>** is CR<sub>26</sub>;

**R<sub>7</sub>** is NR<sub>26</sub>;

**R<sub>8</sub>** is N;

**R<sub>26</sub>, R<sub>15</sub>, R<sub>12</sub> and X** are each as defined in claim 34;

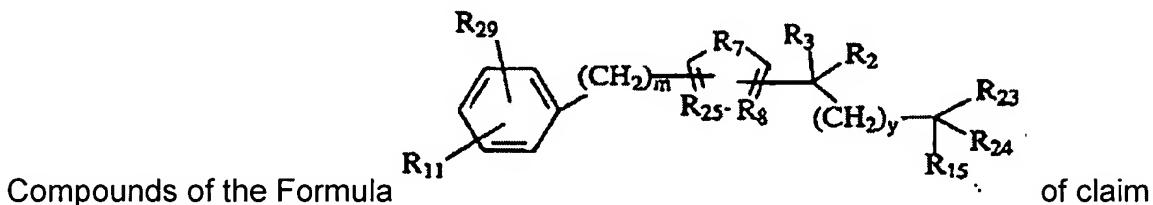
**y** is as defined in claim 34;

**m** is 0;

**p** and **q** are each as defined in claim 34.

Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:



34, wherein:

**R**<sub>25</sub> is O, S, CHR<sub>26</sub>, NR<sub>26</sub> and N;

**R**<sub>7</sub> is O, S, CHR<sub>26</sub>, N or CR<sub>26</sub>;

**R**<sub>8</sub> is O, S, CHR<sub>26</sub>, CR<sub>26</sub> or NR<sub>26</sub>; and

**m** is 1 to 4.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 11-20, 22, 34, 38 and 39 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as pyrrolyl, imidazole, pyrazole, furan, oxazole, thiazole, thiophene, etc. which are chemically recognized to differ in structure, function, and reactivity.

Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the

elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

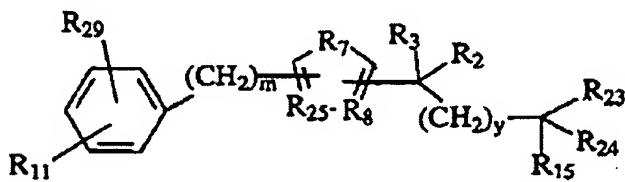
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

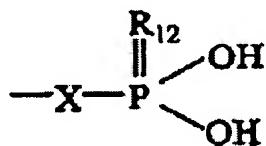
Claims 11-20, 22, 34, 38 and 39 are rejected on the ground of nonstatutory double patenting over claims 1-3 of U. S. Patent No. 7,064,217 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The instant application is drawn to a compound of the formula



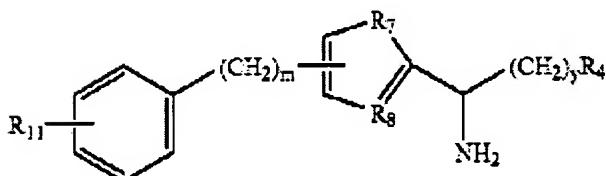
, wherein  $\mathbf{R}_{11}$  is  $\text{C}_5\text{-C}_{12}$  alkyl,  $\text{C}_5\text{-C}_{12}$  alkenyl,  $\text{C}_5\text{-C}_{12}$  alkynyl,  $\text{C}_5\text{-C}_{10}$ (aryl) $\mathbf{R}_{20}$  and  $\text{C}_5\text{-C}_{10}$ (heteroaryl) $\mathbf{R}_{20}$ ;  $\mathbf{R}_{20}$  is H or  $\text{C}_1\text{-C}_{10}$  alkyl;  $\mathbf{R}_{29}$  is H;  $\mathbf{R}_2$  is  $\text{NH}_2$ ;  $\mathbf{R}_3$  is H;  $\mathbf{R}_{23}$  is H;  $\mathbf{R}_{24}$  is H;  $\mathbf{R}_{25}$  is  $\text{CR}_{26}$ ;  $\mathbf{R}_7$  is  $\text{NR}_{26}$ ;  $\mathbf{R}_8$  is N;  $\mathbf{R}_{26}$



is H;  $\mathbf{R}_{15}$  is hydroxy, phosphonate and  
and  $\mathbf{m}$  is 0 to 10.

#### Determining the Scope and Content of the Prior Art

The prior art claims a compound of the formula



, wherein  $\mathbf{R}_{11}$  is  $\text{C}_1\text{-C}_{18}$  alkyl,  $\text{C}_1\text{-C}_{18}$  alkenyl,  $\text{C}_1\text{-C}_{18}$  alkynyl and  $(\text{CH}_2)_n\text{-Z-}\mathbf{R}_6$ ;  $\mathbf{n}$  is 0-10;  $\mathbf{Z}$  is aryl and heteroaryl;  $\mathbf{R}_6$  is H,  $\text{C}_1\text{-C}_{10}$  alkyl;  $\mathbf{R}_4$  is hydroxyl, phosphate, phosphonate, methylene phosphonate, a-substituted methylene phosphonate, phosphate analogs and phosphonate analogs;  $\mathbf{m}$  is 0 to 10;  $\mathbf{y}$  is 1 to 4;  $\mathbf{R}_7$  is N; and  $\mathbf{R}_8$  is N.

#### Ascertaining the Differences Between the Instant Application and the Prior Art

The instant application is broader in certain aspects and narrower in other aspects from the prior art. However, both the prior art and the instant application

substantially overlap. In the variable  $R_{11}$  of the instant application the alkyl, alkenyl and alkynyl groups have only 5-12 carbon atoms. On the other hand, in the prior art these groups have 1-18 carbon atoms. Secondly, they differ in that the instant application has the variables  $R_{23}$ ,  $R_{24}$  and  $R_{15}$  and the prior art has the variable  $(CH_2)_yR_4$ . These differences show that the prior art and the instant application are not drawn to all of the same compounds. Nevertheless, much of the claims cover overlapping subject matter.

*Finding Prima Facie Obviousness*

Both the instant application and the prior art are drawn to compounds and compositions that are sphingosine-1-phosphate analogs that are active in sphingosine-1-phosphate signaling. The prior art patent directs one of ordinary skill in the art to produce the compounds claimed in the instant application. For example, claim 2 of the prior art is drawn to a compound wherein  $R_8$  is N,  $m$  is 0 and  $y$  is 1. Similarly, claim 3 is drawn to a compound of claim 2 wherein  $R_4$  is hydroxyl or phosphate. All of these limitations are claimed in the instant application. Therefore, one of ordinary skill in the art would be motivated to produce the compounds of the instant application with the prior art disclosure.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

***Claim Objections***

Claims 11-20, 22, 34, 38 and 39 are objected to as being drawn to non-elected subject matter.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein  
Patent Examiner, AU 1626

  
For Joseph K. M<sup>c</sup>Kane  
Supervisory Patent Examiner, AU 1626  
Date: September 26, 2006